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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,968	04/20/2001	Michael B. Foster	RENAS/03	1662

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/08/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/838,968	FOSTER, MICHAEL B.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-18 are indefinite because of the use of the term "an agent consisting essentially of", "a response", or "daily basis". The term "an agent consisting essentially of", "a response", or "daily basis" renders the claim indefinite, it is not clear what else is in the agent of recombinant hGH as to "consisting essentially of", use of the term "an agent consisting of" is suggested; what the response is, or, what "daily basis " means, e.g., how many times the agent is administered per day. Claims 2-9, 11-13 and 15-18 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

2. Claims 10-13 are indefinite because of the use of the term "at least one serially increased initial dose of said agent". The term "at least one serially increased initial dose of said agent" renders the claim indefinite, it is unclear how many times the initial dose is going to increase. Claims 11-13 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

3. Claims 2, 3, 11, 15 and 16 are indefinite because of the use of the term "said maintenance dose is administered monthly" or "said optimal dose is administered monthly". The term "said

maintenance dose is administered monthly" or "said optimal dose is administered monthly" renders the claim indefinite, it is unclear why and how would a person administer the same daily dose monthly. Claims 3 and 16 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

4. Claims 5, 6, 8, 9 and 14-18 are indefinite because of the use of the term "about". The term "about" renders the claim indefinite, it is unclear what is the initial dose or maintenance dose as to the term "about". Claims 15-18 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

5. Claim 11 recites the limitation "optimal dose" in line 1. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 12 recites the limitation "bioavailability data" in line 1. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 17 recites the limitation "bioavailability" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 4-10, 12-14 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Chein (U. S. Patent 5,855,920).

Chein teaches a method for replenishing human growth hormone (hGH) in an adult; said method comprising determining the levels of insulin-like growth factor-1 (IGF-1, Somatomedin C) in response to an initial dose of hGH (Col. 10, lines 21-26; Table II; claims 1 (step 1) and 7), and adjusting the dose of hGH until target levels of IGF-1 are achieved by serially increasing doses of hGH administered daily (Col. 11, lines 55-60; Tables III-IV; claim 1 (steps 2 & 3)), establishing the dosage of hGH needed to maintain target IGF-1 levels, and administering the established dose of hGH indefinitely (Col. 11, lines 60-63; Claim 1 (step 4)). Chein teaches that the dose of hGH is to be administered at low dose-high frequency, twice daily (claim 4). Table III of the reference teaches the administration of hGH to males at less than 0.5 mg/day (Col. 12, line 16). Assuming 70 kg (185 lbs), 500 μg/70 kg = 7.1 μg/kg/day, the maintenance dose is "about" 10-14 μg/kg/day (claim 5). Table IV of the reference teaches the administration of hGH to females at less than 0.5 mg/day (Col. 12, line 16). Assuming 48 kg (130 lbs), 500 μg/48 kg = 10.4 μg/kg/day, the maintenance dose is "about" 14-20 μg/kg/day (claim 6). While Chein does not disclose the initial dose of hGH, this dose is less than the maintenance dose. Therefore, Chein discloses administering to males an initial dose of "about" 2 μg/kg/day (claim 8) and to females an initial dose of "about" 4 μg/kg/day (claim 9).

Chein also teaches a method for providing an adult with hGH; said method comprising determining the levels of IGF-1 in response to an initial dose of hGH (Col. 10, lines 21-26; Table II, claim 13), adjusting the dose of hGH until target levels of IGF-1 are achieved by serially increasing doses of hGH administered daily (Col. 11, lines 55-60) and establishing the dosage of hGH needed to maintain target IGF-1 levels, and administering the established dose of hGH indefinitely (Col. 11, lines 60-64; claim 10 and 12).

Chein also teaches a method for optimizing hGH in an adult; said method comprising determining the levels of insulin-like growth factor-1 (IGF-1, Somatomedin C) in response to an initial dose of hGH (Col. 10, lines 21-26; Table II; claim 14 (step 1)), adjusting the dose of hGH until target levels of IGF-1 are achieved by serially increasing doses of hGH administered daily for 3-4 weeks (Col. 11, lines 55-60; Col. 14, lines 44-45; Tables III-IV; claim 14 (steps 2 & 3)), establishing the dosage of hGH needed to maintain target IGF-1 levels, and administering the established dose of hGH indefinitely (Col. 11, lines 60-63; Claim 14 (step 4)). Chein teaches that the dose of hGH is to be administered at low dose-high frequency, twice daily (claim 18). Regarding the rationale for rejection on initial dose of 2 μg/kg/day- 4 μg/kg/day, and maintenance dose of 2 μg/kg/day- 4 μg/kg/day in claim 14, please see the first paragraph under 102 (b) rejection.

While Chein does not expressly teach to administer recombinant hGH at Col. 1, lines 61-64, Chein teaches that recombinant hGH is identical to natural hGH and therefore, the term "recombinant" is given no patentable weight.

The difference between the method of Chein and that of Applicants appears to be in the "daily dose", that is Chein states that hGH should be given twice daily while Applicants administer hGH once daily. Applicants may wish to amend the claims to point out that difference. Also, the doses of Chein appear to be lower than that of Applicants, and deleting the term "about" in the dosage claims would overcome this aspect of the rejection.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

March 6, 2002